AstraZeneca

Date: AUG 3 0 2004

Division of Dockets Management
(HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 2004N-0279
Response to FDA Call for Comments
Drug Information Association/Food and Drug Administration Workshop:
Pharmacogenomic Combination Product Co-Development, Public Meeting

Dear Sir or Madam:

Reference is made to the July 13, 2004 Federal Register notice announcing the request for comments regarding the public meeting held on July 29, 2004: Drug Information Association/Food and Drug Administration Workshop: Pharmacogenomic Combination Product Co-Development.

AstraZeneca has considered the materials and discussions from the forum and our comments are attached.

Please direct any questions or requests for additional information to me at (302)886-1437.

Sincerely,

Brian Abbott

Brian Abbott, Regulatory Project Manager
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Enclosure

2004N-0279 C3

US Regulatory Affairs
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Docket No. 2004N-0279

Drug Information Association/Food and Drug Administration Workshop: Pharmacogenomic Combination Product Co-Development; Public Meeting

General Comments

Comment 1

The Guidance should be clear that the Federal Food, Drug and Cosmetic Act does not require the development of a diagnostic test to gain approval to market a drug product. It should also be clear to the reader that the Guidance applies to those instances where the approval of the drug product is dependent on the identification of a subset of responders through a diagnostic tool to maintain a favorable risk/benefit profile or where the sponsor voluntarily wishes to link the use of the drug product to diagnostic criterion.

Comment 2

The rapid evolution of the science in this area can make it difficult to predefine the appropriate diagnostic during the development phase of a drug. Any guidance at this stage must allow for flexibility; there needs to be an ability to do retrospective analyses and react to scientific breakthroughs during the entire life cycle of the drug product.

Comment 3

Language in the product labeling should be limited to safety and responder data based upon diagnostic test results. Product labeling should not include reference to specific diagnostic kits or their manufacturers.